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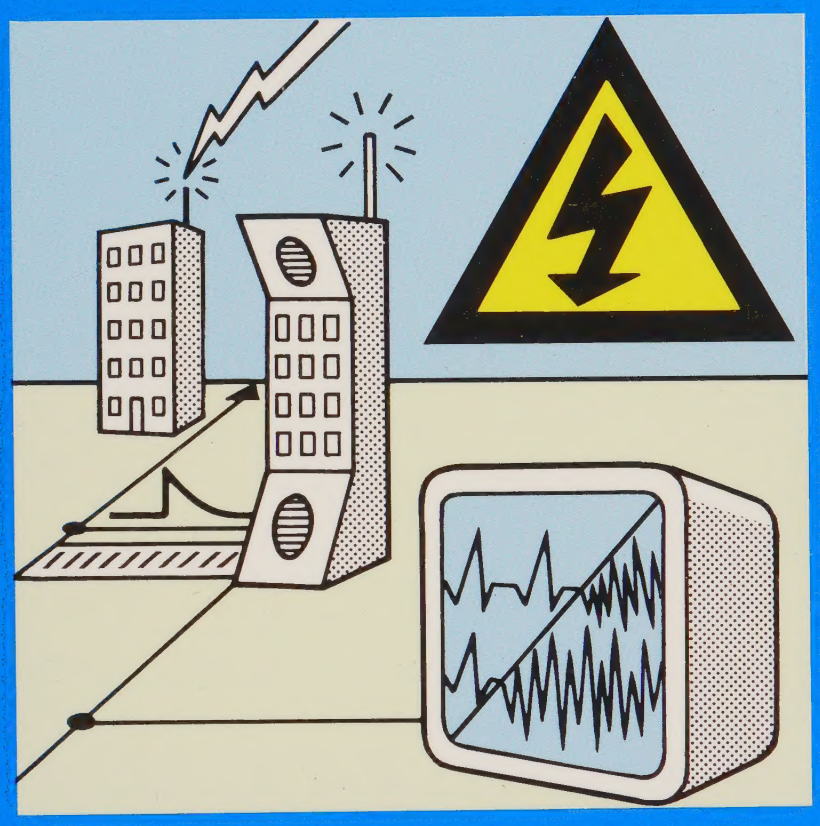
Health Technical Memorandum 2014

Management policy

Abatement of electrical interference



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Health Technical Memorandum 2014

Management policy

Abatement of electrical interference

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About this publication

Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

Health Technical Memorandum 2014

HTM 2014 gives comprehensive advice and guidance on the current and proposed legal and mandatory requirements placed on medical-electrical equipment used in healthcare premises with regard to electromagnetic interference (EMI).

It outlines:

a. the basics of abatement of electrical/electromagnetic interference;

b. the wide-ranging inadvertent interaction of the physical properties between different items of equipment due to EMI.

Advice is given on methods of measurement and containment of electromagnetic interference, and the design and installation practices for the electromagnetic compatibility of medical-electrical equipment within healthcare premises are reviewed.

It is published as four separate volumes each addressing a specialist discipline:

- this volume – **Management policy** – outlines the overall responsibility of managers of healthcare and personal social services premises, and details their legal and mandatory obligations to ensure that all electrical/electronic equipment is purchased and installed in accordance with legal and contractual requirements;

- **Design considerations** – highlights the overall requirements and considerations that should be applied to the design up to the contract document;

- **Validation and verification** – provides information about the

works tests and site tests which have to be carried out to satisfy legal and contractual obligations of the seller and the purchaser. Tests to be done selectively, as required, are listed and the various test instruments are briefly described;

- **Operational management** – simple guidance is given for locating a source of, or the reason for, electromagnetic interference or incompatibility between items of equipment. Guidance is only intended to assist in first-step diagnosis using simple checks and instruments.

Guidance in Health Technical Memoranda is normally complemented by the library of National Health Service Model Engineering Specifications. Users of this guidance are advised to refer to the Statutory Instruments, which outline the standards of manufacture and the obligations of the manufacturer and purchaser.

The contents of this Health Technical Memorandum in terms of management policy and operational policy are endorsed by:

- the Welsh Office for the NHS in Wales;
- the Health and Personal Social Services Management Executive in Northern Ireland;
- the National Health Service in Scotland Management Executive.

References to legislation appearing in the main text of this guidance apply in England and Wales. Where references differ for Scotland and/or Northern Ireland these are given as marginal notes. Where appropriate, marginal notes are also used to amplify the text.

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1.0 Scope

General

1.1 Medical-electrical equipment in healthcare and personal social services premises (HCPs) is liable to be susceptible to electrical interference from:

a. alternating magnetic fields;

b. alternating electric fields;

c. transient voltage changes.

Although distinct types, these interrelate and are generally known as electromagnetic interference (EMI). Electromagnetic compatibility (EMC) is achieved when this interference is eliminated.

1.2 Earlier statutory regulations and British Standards Institution publications dealing with EMI were primarily concerned with preventing various types of electrical equipment (including medical-electrical equipment) from interfering with radio telecommunication services.

1.3 A requirement is now in place for all electrical products, systems and installations not to cause, or be unduly affected by, EMI. The requirement is in the form of an EC Directive on EMC (89/336/EEC as amended by 91/263/EEC and 92/31/EEC). This Directive has been implemented in UK law by the Electromagnetic Compatibility Regulations 1992 (SI No 2372), which came into force on 28 October 1992. Transitional arrangements, until 31 December 1995, are in situ so that member states can continue to allow to be placed on the market, or to be taken into service, apparatus which conforms to the national regulations in force in their territory on 30 June 1992.

1.4 The EMC Directive is not, however, all-inclusive. Apparatus wholly covered by other Directives (for example telecommunication terminal equipment, which has its own specific Directive) is excluded, while medical devices, active implantable medical devices and in-vitro diagnostic devices are, or are expected to be, covered by three specific Directives as follows:

a. active implantable medical devices – 90/385/EEC, UK legislation Active Implantable Medical Devices Regulations 1992 (SI 1992/3146), effective 1 January 1993;

b. medical devices – this is a general Directive on medical devices which was agreed by an EC commission in the summer of 1993 for implementation in January 1995. UK legislation is expected by the end of 1994. A transitional period (during which manufacturers can choose between the old and new systems) will be running until mid 1998;

c. in-vitro diagnostic medical devices – a draft from an EC commission is expected by early 1995.

2.0 Managerial responsibilities

Statutory requirements

2.1 It is the responsibility of the general manager/chief executive to ensure that their premises comply with all statutes.

2.2 Managers of HCPs are obliged to ensure that medical electrical/electronic equipment, systems or installations comply with the requirements of the EC Directives on electromagnetic compatibility.

2.3 EC Directives contain specific requirements, to which products placed on the European market must conform. The EMC Directive applies to all electrical apparatus liable to cause electromagnetic disturbances, or whose performance is liable to be affected by such disturbances. The Directive does not specify the electromagnetic phenomena to be considered and does not specify the test methods nor the limits to be applied. It does require EC member states to recognise conformity in all apparatus which complies with certain standards which have been published in the Official Journal of the European Communities. The EMC Directive has allowed the identification of a number of exclusions; for example apparatus covered by harmonised documents (HDs) in specific Directives is excluded, or will become excluded, when those specific Directives are implemented.

2.4 Apparatus excluded from the EMC Directive is as follows:

a. active implantable medical devices;

b. medical devices;

c. motor vehicles;

d. tractors and agricultural equipment;

e. non-automatic weighing equipment;

f. telecommunications terminal equipment.

2.5 The Active Implantable Medical Devices Directive 90/385/EEC has been adopted by the European Council. It contains full EMC provisions. The transition period (for conformance certification) ends on 31 December 1994. A proposed Directive 91/C237/03 for medical devices has been published in the Official Journal of the European Communities and is under discussion. It will contain full EMC provisions and the proposed implementation date is January 1995. In-vitro medical devices are to be the subject of another specific Directive, which has not at present been formulated.

2.6 The management is required to be aware of this information for the procurement, installation and use in service of medical electrical/electronic equipment, systems and installations.

The EC Directive 89/336/EEC

2.7 The EMC Directive indicates essential equipment protection requirements, and devolves guidance to the International Electrotechnical Commission (IEC), European standards or national standards to define product characteristics in

terms of electromagnetic compatibility between items of apparatus, within systems and in installations.

2.8 The EMC Directive applies to nearly all electrical and electronic apparatus placed on the market in the European Community on or after 1 January 1992 and thus affects manufacturers, distributors and in some cases end-users of electrical/electronic apparatus, systems and installations. Its main purpose is to remove technical barriers to trade, thus assisting in the completion of the single market. Behind this objective lies the genuine need to combat increasing levels of electromagnetic interference between electrical/electronic products, with effects ranging from those with simple nuisance value to major safety hazards. There are a limited number of specific exclusions from the Directive, such as electromagnetically benign apparatus (for example resistors and other passive circuit components) and equipment which is covered, or will be covered, in part or wholly, by other Directives for its EMC aspects, such as motor vehicles and medical devices. Where separate requirements exist but cover only certain electromagnetic phenomena, apparatus will still need to comply with the EMC Directive as regards the other EMI phenomena.

2.9 The scope of the EMC Directive is defined as:

> "all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance".

2.10 Electromagnetic disturbance is defined as:

> "any electromagnetic phenomenon which may degrade the performance of a device, unit of equipment or system. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself".

All electromagnetic frequencies are involved, as are all electromagnetic phenomena. The Directive therefore theoretically applies *a priori* to a vast range of equipment encompassing, as broadly as possible, all electrical/electronic appliances, equipment and installations. However, from the context and a study of the EMC Directive, it is possible to specify the scope more closely.

2.11 Components are outside the scope of the Directive. This applies both to simple components and to complex items, so long as the item in question does not have an intrinsic function and its only purpose is to be incorporated inside the apparatus.

2.12 Systems must meet the requirements of the Directive. A system is defined as "several items of apparatus combined to fulfil a specific objective and intended to be placed on the market as a single functional unit".

2.13 An installation is defined as several combined items of apparatus, or systems, put together in a given place to fulfil a specific objective but not intended to be placed on the market as a single functional unit. Each apparatus or system used in an installation is subject to the provisions of the Directive, and each apparatus of that system must comply with the installation conditions laid down by their manufacturer in order to ensure the proper operation of the installation itself.

2.14 The Directive applies to individual items of apparatus first placed on the European Community market, or first taken into service in the Community, on or after 1 January 1992 even if other items of the same design have been placed on the market or taken into service before that date. Transitional arrangements have

been agreed such that, until 31 December 1995, member states must continue to allow to be placed on the market, or to be put into service, apparatus that conforms to the national regulations in force in their territory on 30 June 1992.

2.15 There are two basic protection requirements to be fulfilled:

a. apparatus must be so constructed that any disturbance it generates allows radio and telecommunication equipment and other apparatus to operate as intended;

b. apparatus must be constructed to provide an adequate level of protection against disturbances, that is, be immune.

2.16 In most cases the methods of satisfying the protection requirements are twofold. Manufacturers must:

a. manufacture in conformity with specified European standards, which will be published in the United Kingdom as identically worded British Standards; or

b. draw up a technical construction file which describes the apparatus, sets out the procedures used to ensure that the apparatus conforms with the protection requirements, and includes a technical report or certificate from a competent body.

2.17 The manufacturer, or his authorised representative established within the Community or, in the absence or either of the above, the person who places the apparatus on the Community market, must then hold that construction file at the disposal of the enforcement authorities in any member state for ten years.

2.18 An attestation must be given that the apparatus has met the protection requirements. The manufacturer, or his authorised representative established within the Community, must certify that the apparatus complies with the Directive by making a declaration of conformity. He must keep the declaration available to enforcement authorities for ten years following the placing of the apparatus on the market. If the manufacturer is not established within the Community and he has no representative so established, the person who places the apparatus on the market has to hold the declaration.

2.19 The manufacturer or his authorised representative established within the Community must also affix the CE mark to the apparatus, or else to the packaging, the instructions for use or the guarantee certificate. The mark is in this form:

2.20 The CE mark is to be accompanied by the figures of the year in which it is affixed and, where appropriate, the distinctive letters of the approved body that issued the EC type-examination certificate. The mark also indicates that the apparatus complies with other Directives relevant to the product and requiring the CE mark.

2.21 The European Commission has proposed a measure on the affixing and use of the CE mark. If adopted, such a measure may change the provisions of the EMC Directive on the CE mark.

2.22 Member states must take all appropriate measures to ensure that apparatus is placed on the market or taken into service only if it complies with the Directive when it is properly installed and maintained, and used for its intended purpose.

2.23 Unless there is evidence to the contrary, member states must presume that apparatus which conforms to relevant specified European standards or to relevant approved national standards, or for which a technical construction file exists, and which bears a CE mark, complies with the protection requirements.

2.24 Failure to comply with these requirements will be made a criminal offence within the EC.

2.25 Safeguard procedures are in place such that each member state is required to take all appropriate measures to withdraw from the market, or restrict the free movement of, apparatus bearing a CE mark but not complying with the protection requirements. The member state must immediately inform the European Commission of its action, giving reasons. The Commission must consult the parties concerned as soon as possible and, where it finds the action justified, is to inform member states forthwith.

2.26 Member states may take special measures concerning the taking into service and use of apparatus for a specific site in order to:

a. overcome an existing or predicted EMC problem; or

b. with regard to the installation of the apparatus, to protect the public telecommunications network or stations used for safety purposes.

Member states are required to inform the European Commission and the other member states of such special measures, and the Commission is to give notice of special measures that have been recognised as justified in the Official Journal of the European Communities.

EC Directives for medical devices

2.27 A Directive 90/385/EEC exists for active implantable medical devices and was first adopted by the European Council in June 1990. The implementation date is 1 January 1993, with the transition period ending on 31 December 1994. The scope of this Directive will cover all powered implants including powered partial implants that are left in the human body. This Directive is to cover all EMC aspects and the EMC Directive 89/336/EEC will not apply.

2.28 A specific Directive is being prepared, proposal 91/C237/03, for medical devices generally, and the EMC aspects of these devices will be covered within that Directive. The EMC Directive 89/336/EEC will not apply to the devices under this Directive. The scope of this document is said to range from first-aid bandages to CT scanners; the proposed implementation date for this Directive is January 1995.

2.29 The in-vitro diagnostic medical devices Directive has been proposed for any medical device, reagent, reagent product, kit, instrument, apparatus or system which is intended to be used in-vitro for the examination of substances derived from the human body. It will be at least 1996 before it takes effect.

2.30 All other apparatus pertinent to HCPs is subject to the EMC Directive 89/336/EEC. Telecommunications terminal equipment (TTE) is subject to a specific Directive 91/263/EEC which covers dedicated telecommunications EMC requirements. EMC provisions not covered by the TTE Directive or other specific Directive must be subjected to the EMC Directive 89/336/EEC.

Definitions

2.31 The following definitions apply throughout this document.

2.32 Management: is the owner, occupier, employer, general manager, chief executive, or other person who is accountable for the premises and is responsible for issuing or implementing a general policy statement under the Health and Safety at Work etc Act 1974.

Health and Safety at Work (Northern Ireland) Order 1978 SI 1979/1039 NI 9.

2.33 Employer: any person or body who:

a. employs one or more individuals under a contract of employment or apprenticeship;

b. provides training under the schemes to which the Health and Safety (Training for Employment) Regulations 1988 (Statutory Instrument No 1988/1222) apply.

Northern Ireland: Health and Safety (Training for Employment) Regulations 1990, Statutory Instrument No 1990/1380.

2.34 Department: an abbreviation of the generic term "UK Health Departments" (Department of Health, the Scottish Office, the Welsh Office and the Department of Health and Social Services Northern Ireland).

2.35 Duty holder: a person on whom the Electricity at Work Regulations 1989 impose a duty in connection with safety.

Electricity at Work Regulations (Northern Ireland), 1991 (SI 191/13) Enforcement date 6 January 1992.

2.36 Electrical/Electronic equipment: includes anything used, intended to be used or installed for use to generate, provide, transmit, transform, conduct, distribute, control, measure or use electrical energy.

2.37 Equipment: abbreviation of electrical/electronic equipment.

2.38 System: a system in which all the electrical equipment is, or may be, electrically connected to a common source of electrical energy, including such source and such equipment.

2.39 High voltage (HV): the existence of a potential difference (rms value for ac) normally exceeding 1000 volts ac between circuit conductors or 600 volts between circuit conductors and earth.

2.40 Low voltage (LV): the existence of a potential difference (rms value for ac) not exceeding 1000 volts ac or 1500 volts dc between circuit conductors or 600 volts ac or 900 volts dc between circuit conductors and earth.

2.41 Ambient level: those levels of radiated and conducted signal noise existing at a specified test location and time when the test sample is inoperative. Atmospherics, interference from other sources, circuit noise, or other interference generated within the measuring set comprise the "ambient level".

2.42 Antenna-induced voltage: the voltage that is measured or calculated to exist across the open-circuited antenna terminals.

2.43 Broadband emission: emission which has a spectral energy distribution sufficiently broad, uniform and continuous so that the response of the measuring receiver in use does not vary significantly when tuned over a specified number of receiver impulse bandwidths.

2.44 Conducted emission: desired or undesired electromagnetic energy which is propagated along a conductor. Such an emission is called "conducted interference" if it is undesired.

2.45 Cross coupling: the coupling of a signal from one channel, circuit or conductor to another, where it becomes an undesired signal.

2.46 Cross modulation: modulation of a desired signal by an undesired signal. This is a special case of intermodulation.

2.47 Crosstalk: an electromagnetic disturbance introduced by cross coupling.

2.48 Electromagnetic compatibility: capability of electronic equipment or systems to be operated with a defined margin of safety, in the intended operational environment, at designed levels of efficiency, without degradation due to interference.

2.49 Emission: electromagnetic energy propagated from a source by radiation or conduction. This may be intentional or unintentional emission.

2.50 Field strength: the term "field strength" should be applied only to measurements made in the far field. The measurement may be of either the electric or the magnetic component of the field, and may be expressed as volts per metre, amperes per metre, or watts per square metre; any one of these may be mathematically converted to the others.

2.51 Earth plane: a metal sheet or plate used as a common reference point for circuit returns and electrical or signal potentials.

2.52 Impulse: an electromagnetic pulse of short duration relative to a cycle at the highest frequency being considered. Regularly repeated impulses of uniform level will generate a uniform spectrum of discrete frequencies (Fourier components), separated in frequency by an amount equal to the repetition frequency.

2.53 Impulse bandwidth: the peak value divided by the area of the impulse response envelope.

2.54 Impulse emission: emission produced by impulses having a repetition frequency not exceeding the impulse bandwidth of the receiver in use.

2.55 Interference emission: any undesirable electromagnetic emission.

2.56 Intermodulation: mixing of two or more signals in a nonlinear element, producing signals at frequencies equal to the sums and differences of integral multiples of the original signals.

2.57 Narrowband emission: that which has its principal spectral energy lying within the bandpass of the measuring receiver in use.

2.58 NAMAS: a specialist NPL test executive approved under the auspices of the National Measurement Accreditation Scheme to accredit test laboratories to undertake EMC testing.

2.59 Open area: a site for radiated electromagnetic interference measurements which consists of open flat terrain at a distance far enough away from buildings, electric lines, fences, trees, underground cables and pipelines so that effects due to these are negligible. This site should have a sufficiently low level of ambient interference to permit testing to the required limits.

2.60 Radiated emission: radiation and induction field components in space.

2.61 Spurious emission: any electromagnetic emission from the intended output terminal of an electronic device, but outside the designed emission bandwidth.

2.62 Spurious response: any response of an electronic device to energy outside its designed reception bandwidth through its intended input terminal.

2.63 Standard reference output: a condition for a particular test sample that defines normal operation and is used in measuring any deviation from standard performance that occurs during susceptibility testing. This value should be indicated in the individual equipment specification.

2.64 Susceptibility: the characteristic of electronic equipment that permits undesirable responses when subjected to electromagnetic energy.

2.65 Test antenna: an antenna of specified characteristics designed for use under specified conditions in performing tests.

3.0 Organisation of statutory requirements

3.1 The worldwide organisation for standards is the International Electrotechnical Commission (IEC). The IEC is comprised of representatives from over 40 national electrotechnical committees. The International Special Committee on Radio Interference (CISPR) was formed in 1934 as a committee of the IEC. The CISPR has six subcommittees which prepare and manage the various standards and regulations.

3.2 CENELEC, the European electrotechnical standardisation body, has been given a mandate by the European Commission to draw up standards to be used for compliance with the EMC Directive. A number of generic and product-specific standards are currently being drawn up, and the first of these are already in place. See Table 1.

3.3 It is intended that there will be three types of standard for the EMC Directive:

a. product standard relating to a specific product;

b. product family standard, relating to a specific product group;

c. generic standard, relating to a particular location of operation.

3.4 Where a product standard exists, it will take precedence over a generic standard, but it is expected that most apparatus will be governed by generic standards because the number of product standards is likely to be small.

3.5 ETSI, the European Telecommunications Standards Institute, formulate standards which relate to EMC for radio telecommunications apparatus.

National standards

3.6 British Standards are produced by the British Standards Institution (BSI). It has a common structure to that of the IEC committees in the UK. The British member body of the IEC and CENELEC is the British Electrotechnical Committee (BEC). When dealing with international documents, commenting or voting, the BSI electrical committees do so on behalf of the BEC. The BSI Technical Committee GEL/110 is responsible for international documents and for British Standards relating to electromagnetic interference in connection with the EC Directives. Current EMC national standards are given in Table 2.

Statutory Instruments

3.7 In order to protect radio services, internationally agreed statutory limits are enforced for the field strength of radiated interfering signals at radio designated frequencies and for the magnitude of supply mains terminal transient voltages. Special frequencies are allocated for industrial, scientific and medical purposes (ISM frequencies) and unlimited radiation energy is permitted on these frequencies. Data processing equipment is also included in the ISM range of frequencies.

3.8 The regulations concerning radio interference have hitherto been published in the United Kingdom as Statutory Instruments (SI) under the direction of the Department of Trade and Industry (DTI). See Table 2 for current Statutory Instruments. New UK regulations, EMC Regulations 1992, will replace existing Statutory Instruments for EMC.

Table 1 Principal European Standards (EN)

CENELEC reference	Contents	BS No or new draft work	International reference
Pr EN 50061:1990	Cardiac Pacemakers	New Clause 6.3	90/50313 DC
EN 50065-1:1991	Mains Signalling on Low Voltage Installations	BS EN 50065-1:1992	
EN 50081-1:1992	Generic Emission Standard: Domestic Commercial and Light Industry	EN 50081-1:1992	
Pr EN 50081-2:1991	Generic Emission Standard: Industrial	91/21829 DC	
EN 50082-1:1992	Generic Immunity Standard: Domestic Commercial and Light Industry	BS EN 50082-1:1992	
Pr EN 50082-2:1991	Generic Immunity Standard: Industrial	91/21828 DC	
EN 55011:1991	RFI Characteristics: Industrial, Scientific and Medical Equipment	BS EN 55011:1991	CISPR 11
EN 55013:1990	Sound and TV Broadcast Receivers and Associated Equipment	BS905:1991 Part 1	CISPR 13
EN 55014:1987	RFI Characteristics: Household Appliances, Portable Tools and Similar	BS800:1988 Proposed Revision 90/20911 DC	CISPR 14
EN 55015:1987	RFI Characteristics: Fluorescent Luminaires	BS5394:1988 Proposed Revision 90/22423 DC	CISPR 15
EN 55020:1988	Sound and TV Receivers and Associated Equipment	BS905:1991 Part 2 Proposed 91/25187	CISPR 20
EN 55022:1987	RFI Characteristics: Information Technology Equipment	BS6527:1988	
Pr EN 55024-1	Immunity ITE: General Introduction (Replaces Pr EN 55101-1)		CISPR 24-1*
Pr EN 55024-2	Immunity ITE: Electrostatic Discharge (Replaces Pr EN 55101-2)	89/34172 DC	CISPR 24-2*
Pr EN 55024-3	Immunity ITE: Immunity Against Radiated Radio Frequency Disturbances (Replaces Pr EN 55101-3)	89/34171 DC	CISPR 24-3*
Pr EN 55024-4	Immunity ITE: Immunity Against Transients (Replaces Pr EN 55101-5)		CIPSR 24-4
Pr EN 55024-6	Immunity ITE: Immunity Against Conducted Signals (Replaces Pr EN 55101-4)	90/30270 DC	CISPR 24-6
HD 481.1.SI:1987	EMC Industrial Measurement and Control: General	BS6667:1985 Part 1	See also IEC 801-1
HD 481.2.SI:1987	Immunity ITE: Electrostatic Discharge	BS6667:1985 Part 2	See also IEC 801-2
HD 481.3.SI:1987	Immunity ITE: Immunity Against Radiated Signals	BS6667:1985 Part 3	See also IEC 801-3
Pr EN 55101-1		†	
Pr EN 55101-2		†	
Pr EN 55101-3		†	
Pr EN 55101-4		†	
Pr EN 55101-5		†	
EN 60555-1:1987	Disturbances in Supply Systems by Household and Similar Equipment Part 1 Definitions	BS5406:1988 Part 1	IEC 555-1
EN 60555-2:1987	Disturbances in Supply Systems by Household and Similar Equipment Part 2 Harmonics	BS5406:1988 Part 2	IEC 555-2
EN 60555-3:1987	Disturbances in Supply Systems by Household and Similar Equipment Part 3 Voltage Fluctuations	BS5406:1988 Part 3	IEC 555-3

** Not yet available*

† It is proposed to re-number these standards in line with EN 55024 above.

Table 1 – continued

CENELEC reference	Contents	BS No or new draft work
Pr EN 50083-2: 1991	Cable distribution systems for television and sound signals. Part 2: Electromagnetic compatibility for components and system	91/31337 DC
Pr EN 50093:1991	Basic immunity standard for voltage dips, short interruptions and voltage variations	91/29431 DC
Pr EN 50096	Equipment with integrated services digital network. Equipment with ISDN user-network interface at basic and primary – EMC requirements (Pr ETS 300126:1991)	
Pr EN 50098	Equipment engineering – Radiated emission testing of physically large telecoms (Pr ETS 300127:1991)	
EN 55014 Amendment 2: 1990	Limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus (includes amendments 1, 4, 5, 6, 7 and 8, amendment 3 was withdrawn)	
Pr EN 55014	Draft amendments Pr AM9, Pr AM10, Pr AM11, Pr Am12 and Pr AM13 (Approved for formal vote)	
Pr EN 55014 Edition 2	Limits and methods of measurement of radio disturbance characteristics of electrical motor-operated and thermal appliances for household and similar purposes, electrical tools and similar electric apparatus (formal vote launched). Based on future CISPR 14 Edition 3	
EN 55015 Amendment 1: 1990	Limits and methods of measurement of radio interference characteristics of fluorescent lamps and luminaires (Amendment to sub-clause 4.2 of CISPR 15)	90/22423 DC
Pr EN 55022 Amendment 1: 1987	Limits and methods of measurement of radio interference characteristics of information technology equipment. Issued as: 87/28339. Based on: CISPR 22: 1985	
Pr EN 55022 Amendments: 1990	Limits and methods of measurement of radio interference characteristics of information technology equipment. Issued as: 87/28339. Based on: CISPR 22: 1985	
Pr EN 55022 Amendments: 1990	Limits and methods of measurement of radio interference characteristics of information technology equipment	90/27028 DC
Pr EN 55022	Draft amendment	89/34612 DC
Pr EN 55022	Draft amendment	89/34613 DC
Pr EN 55022	Draft amendment	90/20099 DC
EN 60555-3 Amendment 1: 1990	Disturbances in supply systems caused by household appliances and similar electrical equipment. Part 3: Voltage fluctuations (with corrigendum 1990)	
Pr EN 61000-2-2: 1991	Electromagnetic compatibility (EMC) Part 2: Environment Section 2 – Compatibility levels for low-frequency conducted distrubances and signalling in public low-voltage power supply systems. Based on: IEC 1000-2-2	
Pr En 61000-4-7	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques. Section 7: General guide on Harmonics, Interharmonics Measurements and Instrumentation, for power supply systems and equipment connected thereto. Based on: IEC 1000-4-7	
Pr EN 61000-4-4	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques. Section 8: Power frequency magnetic field immunity test. Basic EMC publication. Based on IEC 1000-4-8	
Pr EN 61000-4-9	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques. Section 9: Pulse magnetic field immunity test; Basic EMC publication	
Pr EN 61000-4-10	Electromagnetic compatibility (EMC) part 4: Testing and measurement techniques. Section 10: Damped oscillatory field immunity test	
Pr EN 60601-1-X	Medical Electrical Equipment Part 1: General Requirements for Safety – Collateral Standard, Electromagnetic Compatibility for information only: this document was first identified as Pr EN 50097:1991	
Pr ETS 300 126: Draft November 1990	Integrated services digital network with (ISDN) equipment with ISDN interface at basic and primary rate EMC requirements (DE/EE-4001)	
Pr ETS 300 127: Draft November 1991	Equipment engineering: Radiated emissions testing of physically large systems (DE/EE-4002)	

Table 2 National Standards

Standard Organisation: British Standards Institution
BS EN 55011 (EN 55011)
BS905 Part 1 (EN 55013)
BS800 (EN 55014)
BS5394 (EN 55015)
BS905 Part 2(EN 55020)
BS6527 (EN 55022)
BS5406 Part 1 (EN 60 555-1)
BS5406 Part 2 (EN 60 555-2)
BS5406 Part 3 (EN 60 555-3)
BS6667 Part 1 (IEC 801-1)
BS6667 Part 2 (IEC 801-2)
BS6667 Part 3 (IEC 801-3)
BS6299 (CISPR 17)
BS727: 1983 Specification for Radio Interference Measuring Apparatus (based on CISPR 16)
BS833:1970 Specification for Radio Interference Limits and Measurements for the Electrical Ignition Systems of Internal Combustion Engines (based on CISPR 12 and CISPR 21)
BS5049:1987 Methods of Measurement of Radio Interference Characteristics of Overhead Power Lines and High Voltage Equipment (based on CISPR 18-2)
BS5260:1975 Code of Practice for Radio Interference Suppression on Marine Installations
BS5602:1978 Code of Practice for Abatement of Radio Interference from Overhead Power Lines (based on CISPR 1, CISPR 18-1, CISPR 18-3, CISPR Report 44)
BS6345:1983 Method for Measurement of Radio Interference Terminal Voltage of Lighting Equipment (based on CISPR 15)
Existing regulations are listed below (Statutory Instrument Numbers)
1952 No 2023 The Wireless Telegraphy (Control of Interference from Ignition Apparatus) Regulations 1952 (superseded by 1973 No 1217)
1955 No 291 The Wireless Telegraphy (Control of Interference from Electric Motors) Regulations 1955 (superseded by 1978 No 1267)
1955 No 292 The Wireless Telegraphy (Control of Interference from Refrigerators) Regulations 1955 (superseded by 1978 No 1267)
1963 No 1895 The Wireless Telegraphy (Control of Interference from Electro-medical Apparatus) Regulations 1963
1971 No 1675 The Wireless Telegraphy (Control of Interference from Radio Frequency Heating Apparatus) Regulations 1971
1973 No 1217 The Wireless Telegraphy (Control of Interference from Ignition Apparatus) Regulations 1973
1978 No 1267 The Wireless Telegraphy (Control of Interference from Household Appliances, Portable Tools, etc) Regulations 1978 amended by 1985 No 808 and 1989 No 562
1978 No 1268 The Wireless Telegraphy (Control of Interference from Fluorescent Lighting Apparatus) Regulations 1978 amended by 1985 No 807 and 1989 No 561
1988 No 1957 The Electricity Supply Regulations 1988
1992 No 2372 The Electromagnetic Compatibility Regulations

4.0 Applicable standards

Household and commercial appliances

4.1 These appliances form one category of the wide-ranging items which cause radio or supply inteferences. Unscreened interferences usually emanate from small motors/switching devices and regulating controls containing semiconductors. The CISPR has produced Publication 14 as a guidance document.

4.2 The EC Directive published in 1976, amended 1982, was implemented in the UK as a Statutory Instrument (1978 No 1267). This SI refers to BS800:1983 (EN 55014), 'Specification for radio interference limits and measurement for household appliances, portable tools and other electrical equipment, causing similar types of interference in telecommunication equipment'. The scope of BS800 defines the limits of radio interference permitted from/by repetitive interference signals, lasting more than 200 milliseconds, and expressed as terminal voltage limits in the frequency range 0.15 to 30.0 MHz, and as interference power levels in the frequency range 30 to 300 MHz. A revision of BS800:1988 has been proposed (90/20911 DC).

4.3 The limitation of disturbances in electricity supply networks caused by domestic or similar appliances, equipped with electronic devices is referred to in BS5406:1988 (EN 60555).

Fluorescent lighting

4.4 The CISPR Publication 15 specifies limits of interference signals caused by fluorescent lighting controlled by starter units. A Statutory Instrument 1978 No 1268 refers to BS5394:1988 (EN 55015: 1987). Specification for radio interference states limits and measurements for luminaires using tubular fluorescent lamps fitted with starters. A revision of BS5394 has been proposed (90/22423 DC).

Industrial, scientific and medical (ISM)

4.5 This equipment is permitted to produce intentional radio frequency signals as part of the function of the equipment, that is, inductive heating, arc welding and surgical diathermy. Refer to Table 3.

4.6 There is considerable debate and disagreement, in relation to CISPR Publication No 11, between ISM manufacturers, communication and navigational operators. Data transmission and communications equipment using digital techniques, and therefore having a wide bandwidth susceptiblity, is subject to encroachment from healthcare surgical diathermy equipment interference. In the UK there is one SI concerning electro-medical equipment: 1963 No 1895.

Electro-medical equipment

4.7 Special frequencies are allocated for industrial, scientific and medical (ISM) purposes and unlimited radiation is permitted at certain frequencies. In the special case of surgical diathermy, there is no restriction for either frequency or power output.

4.8 The interference limits specified in the Wireless Telegraphy (Control of interference from electro-medical apparatus) Regulations 1963 No 1895 are given in Table 3.

Data processing equipment/information technology equipment

4.9 The British Electro-technical Committee (BEC) produced BS6527:1988, 'Specifications for limits and measurements of spurious signals generated in data processing and electronic office equipment'. This BS is equivalent to EN 55022 and has sufficient technical content to be used internationally. The standard specifies terminal voltage limits at the mains terminals in the 0.15–30 MHz frequency range, and limits radiated frequency field strength in the 30–300 MHz frequency range for domestic and commercial users. Draft product specifications are under discussion as Pr EN 55024 parts 1 to 6. Other relevant harmonised documents are HD 481 series, equivalent to BS6667:1985.

TV and sound broadcast receivers

4.10 Sub-committee E of CISPR is responsible for limits of interference caused by TV and sound broadcast receivers and, uniquely within CISPR, is also responsible for immunity. Publication 13 specifies limits of interfering signals and has some limits for immunity over the 150–1605 KHz range. There is also considerable work going on at present within CISPR sub-committee E on immunity. Whilst there is no EC Directive or CENELEC standard, there is some intention to adopt CISPR results.

4.11 BS905:1985, 'Limits of radio frequency and immunity' was revised and published in two parts and is equivalent to EN 55013 and EN 55020. Part 1 (EN 55013) specifies limits of radio interference over a frequency range of 0.15–1000 MHz, some being expressed as voltage limits measured at the mains terminals, some as limits at the antenna and other limits for local oscillator radiation. Part 2 (EN 55020) specifies immunity limits of receivers and associated equipment in the 26–30 MHz range, and of TV receivers to tuned frequency interference or "ghosting". Part 2 in particular contains much new work, and was derived from CISPR sub-committee E.

Internal-combustion engine ignition

4.12 Once a great source of annoyance, the internal-combustion engine's problems are largely solved as far as broadcast reception is concerned. CISPR sub-committee D has produced Publication 12; and, upon joining the Common Market, the UK inherited a 1972 EC Directive 72/45/EEC. This is implemented in the UK by a Statutory Instrument (1973 No 1217) which in turn refers to BS833:1970 (1985). The latter specifies limits of radiation over the 40–250 MHz frequency band.

Public supply mains

4.13 Sub-committee C of CISPR is proposing, in Publication 18, recommendations on the limits of interference caused by power lines. The UK already has BS5602:1978 which is a code of practice for the abatement of such interference in overhead power lines.

4.14 There is also a CENELEC EN 60555, equivalent to BS5406:1976 (1985), which recommends limits of disturbance to the public supply caused by domestic appliances. A draft revision Pr EN 50093:1991 has been proposed for basic immunity standard for voltage dips, short interrupts and voltage variations.

Table 3 ISM Frequency bands

Frequency range	Max field strength microvolts per metre at 30 metres	Max mains terminal voltage in microvolts
150 KHz – 40 MHz (excluding ISM frequencies)	30	1500
40 MHz – 118 MHz	15	750
118 MHz – 223 MHz	30	1500
13.56 MHz ± 0.05% (ISM frequency)	Unlimited	Unlimited
27.12 MHz ± 0.6% (ISM frequency)	Unlimited	Unlimited

Limits for the field strength and terminal voltage of harmonics of 13.56 MHz are also given.

5.0 Electromagnetic interference

5.1 The increased use of sophisticated technology in healthcare and social services premises (HCPs) has resulted in a need to combat increasing levels of electromagnetic interference (EMI) between electrical/electronic products, with effects ranging from simple acceptable nuisance value to major safety hazards. Unacceptable nuisance effects and potential hazards due to EMI have resulted in the demand for a higher degree of reliability in all electronic/electrical apparatus including battery and/or mains voltage-driven electronic equipment, with the special requirement that all apparatus, systems and installations operate free from externally or internally generated electromagnetic interference.

Physical aspects

5.2 The source of interference, and its relationship to other susceptible equipment, divides naturally into three separate components as follows:

a. the source of the interference – the aggressor;

b. the equipment which is affected – the victim or susceptible equipment;

c. the path by which the source of interference is coupled to the affected equipment.

The source of interference

5.3 This is the aggressor device. It generates extraneous electromagnetic fields or produces undesired mains transient energy. This energy may be expressed in terms of watts and may be evaluated in volts and amps for conducted interference, or as volts per meter or amperes per meter for radiated field distribution pattern.

The susceptible equipment

5.4 This is the susceptible device. It has produced an undesired response to an interference signal.

The coupling path

5.5 This is the medium through which the energy of interference is transferred from the source to the victim. It is passive but it may be linear or non-linear electrically in its characteristic behaviour to that interference signal.

5.6 The transfer of an interference signal may be conducted electrically by wire, field induced magnetically as a near field effect, or electric field radiated as a far field effect.

5.7 Low frequency magnetic field interference is predominantly inductively transferred, whereas high frequency electric field interference is predominantly capacitively coupled between source and victim.

5.8 Electromagnetic field radiation is transferred in the form of a travelling wave, emanating from the energy source (for example radio transmitting antenna). The speed of wave travel is determined by the characteristic impedance of the medium through which the wave travels. For free space, the characteristic impedance is

$$Z_o = \sqrt{(\mu_o/\varepsilon_o)} \approx 377 \text{ ohms}$$

For free space the velocity of a wave is given by

$$v_o \approx \sqrt{(\mu_o\, \varepsilon_o)} = 3 \times 10^8 \text{ ms}^{-1}$$

(the velocity of light)

where v_o = permeability of free space

ε_o = permittivity of free space.

Psychological requirement and tolerance

5.9 The level of tolerance to any interference signal seen or heard from an item of equipment depends upon the sensitivity or response of the victim equipment, and the skill by which the victim can clearly and accurately separate the desired signal information from the sum of the observed signal. The ratio of "desired signal strength" to "interference strength" is defined as "signal-to-noise" ratio (Sn):

$$Sn = \frac{\text{signal strength in watts}}{\text{interference strength in watts}}$$

5.10 There is no absolute requirement to remove all interference from the information signal in every situation. The need to obtain a higher level of information signal purity becomes progressively more costly.

5.11 It is essential that all equipment continues to function in a safe and reliable manner. Each item of equipment, system or installation will have its own tolerance level for safe performance and this level of minimum acceptable performance should not be breached. Reciprocally, no equipment, system or installation should cause the malfunction of any other equipment, system or installation. Exceptions to the rule are closely governed: details are given in section 2.0 of this document.

6.0 Management action

6.1 Managers of healthcare and social services premises (HCPs) are required to be aware of, and understand, the basic concepts of electromagnetic interference and to provide an overview of managerial responsibility, guidance and expectations with regard to existing Statutory Instruments.

6.2 Managers of HCPs are required to be aware of the implications of the EMC Directive 89/360/EEC for the procurement of medical-electrical apparatus and systems, and the installation requirements stipulated by the manufacturer for proper operation of the installation.

6.3 Medical and technical staff who are to operate medical electronic and electrical equipment in HCPs should be given support knowledge to understand the effects of mains-borne and electromagnetic interference upon the equipment.

6.4 Engineers who are responsible for the design, preparation of specifications and purchase of all types of electrical equipment for healthcare and social services premises should make suppliers fully aware of their requirements and ensure that performance guarantees and test certificates are provided by the manufacturer of the equipment within the contract terms.

6.5 Architects who are responsible for the layout and structural planning of HCPs should consult with design engineers on the spatial layout required for equipment, particularly those spaces where large active sources of electromagnetic interference will be generated.

6.6 Manufacturers providing general and medical electronic and electrical equipment should develop an understanding of HCPs' requirements and of the various types of equipment therein.

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3 –
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19 Facsimile telegraphy: the transmission of pathology reports within a hospital – a case study†
2020 Electrical safety code for low voltage systems, 1993.
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22 Piped medical gases, medical compressed air and medical vacuum installations*†
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23 Access and accommodation for engineering services†
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26 Commissioning of oil, gas and dual fired boilers: with notes on design, operation and maintenance†
27 Cold water supply storage and mains distribution* [Revised version will deal with water storage and distribution], 1978.
28 to 39 –
2040 The prevention of legionellae in healthcare premises – a code of practice
41 to 52 –

Component Data Base (HTMs 54 to 70)

54 User manual, 1989.
55 Windows, 1989.
56 Partitions, 1989.
57 Internal glazing, 1989.
58 Internal doorsets, 1989.
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62 Demountable storage systems, 1989.
63 Fitted storage systems, 1989.
64 Sanitary assemblies, 1989.
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66 Cubicle curtain track, 1989.
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68 Ducts and panel assemblies, 1993.
69 Protection, 1993.
70 Fixings, 1993.
71 to 80 –

Firecode

81 Firecode: fire precautions in new hospitals, 1987.
81 Supp 1, 1993.
82 Firecode: alarm and detection systems, 1989.
83 Fire safety in health care premises: general fire precautions*†
85 [Revision to Home Office draft guidance in preparation]
86 Firecode: assessing fire risks in existing hospital wards, 1987.
87 Firecode: textiles and furniture, 1993.
88 Fire safety in health care premises: guide to fire precautions in NHS housing in the community for mentally handicapped/ill people, 1986.

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Health Technical Memorandum 2014 supersedes HTM 14 of the same title published in 1965. It gives comprehensive advice and guidance on the current and proposed legal and mandatory requirements placed on medical-electrical equipment used in healthcare premises with regard to electromagnetic interference (EMI).

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